3.2 Medical Requirements Overview

TABLE 3.2: MEDICAL REQUIREMENTS OVERVIEW

MEDB# and Title:	MEDB N3.06 Nutritional Assessments
Sponsor:	Medical Operations
Discipline:	Nutrition
Category:	Medical Requirements
References:	SSP 50260 ISS Medical Operations Requirements Document (MORD) SSP 50667 Medical Evaluations Document (MED) Volume B
Purpose/Objectives:	Nutritional assessment is required to determine adequacy of nutrient stores prior to flight, to assess nutrient intake and status during flight, and to assure correction of nutritional status following flight. Assessment of body composition is required to determine changes in muscle and bone compartments during space flight.
Measurement Parameters:	Dietary intake, biochemical indices of nutritional status and anthropometric information.
Deliverables:	Dietary intake and body composition data; indices of: protein, calcium/bone, antioxidant, iron, mineral, and vitamin status; blood chemistry and renal stone risk profile data, and MAT report to Crew Surgeon.
Flight Duration:	≥ 30 days
Number of Flights:	All Flights
Number and Type of Crew Members Required:	All Crewmembers
Other Flight Characteristics:	N/A

3.3 Preflight Training

TABLE 3.3: PREFLIGHT TRAINING

<table>
<tr><td>Preflight Training Activity Description:</td><td colspan="4">Familiarization and training will be conducted. The familiarization sessions will include an overview of all nutritional assessment procedures. Training will include hands-on use of the FFQ. Review of FFQ procedures will be provided in a refresher session. Training for the use of the MMD will be provided per MEDB 1.13.</td></tr>
<tr><td rowspan="3">Schedule:</td><td>Duration:</td><td>Schedule:</td><td>Flexibility:</td><td>Personnel Required:</td></tr>
<tr><td>Familiarization and FFQ Training
75 minutes</td><td>AME L-21/18 m</td><td rowspan="2">No additional flexibility outside of specified range</td><td rowspan="2">Instructors/Crewmembers</td></tr>
<tr><td>FFQ Refresher
45 minutes</td><td>L-90/30 d</td></tr>
<tr><td rowspan="2">Ground Support Requirements Hardware/Software</td><td colspan="2">Preflight Hardware:</td><td>Preflight Software:</td><td>Test Location:</td></tr>
<tr><td colspan="2">SSC with Food Frequency Questionnaire (FFQ)
Mass Measuring Device (MMD)</td><td>FFQ Questionnaire
N/A</td><td>U.S.
Russia</td></tr>
<tr><td rowspan="4">Training Facilities</td><td>Minimum Room Dimensions:</td><td>Number of Electrical Outlets:</td><td>Temperature Requirements:</td><td>Special Lighting:</td></tr>
<tr><td>8ft x 10ft</td><td>3 (U.S.-110V, Russia-220V)</td><td>Ambient</td><td>None</td></tr>
<tr><td>Hot or Cold Running Water:</td><td>Privacy Requirements:</td><td colspan="2">Other:</td></tr>
<tr><td>Yes - both</td><td>Yes</td><td colspan="2">Tables (2 at 3ft X 6 ft), Chairs (4)</td></tr>
<tr><td>Constraints/Special Requirements:</td><td colspan="4">Training on the use of the MMD is scheduled and conducted by GCTC personnel in Star City (see MEDB 1.13 Body Mass Measurement).</td></tr>
<tr><td>Launch Delay Requirements:</td><td colspan="4">None</td></tr>
<tr><td>Notes:</td><td colspan="4">*Shared with crewmember consent and per the ISSMP Data Sharing Plan, with, 1. Crew Medical Officer Health Status Evaluations (MEDB 1.2) 2. Human Research Facility (HRF).</td></tr>
</table>

3.4 Preflight Activities

TABLE 3.4: PREFLIGHT ACTIVITIES

<table>
<tr><td>Preflight Activity
Description:</td><td colspan="4">Nutritional assessment will include determination of typical dietary intake using standard Dietary Assessment Questionnaire (DAQ). Blood samples and 48 hour void-by-void (VxV) urine pools will be collected for determination of nutritional status, which will include:
Body Mass and Composition — Iron status
Protein status — Mineral status
Calcium /Bone status — General blood chemistry
Antioxidant status — Fat-soluble vitamin status
Water-soluble vitamin status — Renal stone risk

Body composition assessment will include height and DXA. DXA data will be obtained by Bone Densitometry (MEDB 1.11). Data will be examined and the necessity/details of a diet prescription will be assessed.</td></tr>
<tr><td rowspan="3">Schedule:</td><td>Duration:</td><td>Schedule:</td><td>Flexibility:</td><td>Personnel Required:</td></tr>
<tr><td>Nutritional Status Assessment
<u>Day 1</u>
Ht/Wt: 5 min
DAQ: 45 min
VxV urine: 20 min
<u>Day 2</u>
VxV urine: 20 min
<u>Day 3</u>
Close-out void
<u>Day 1, 2, or 3</u>
Blood draw: 10 min</td><td>AME L-21/18 m
Includes body weight/height, DAQ, baseline blood collection and 48 hours of void by void urine collection</td><td rowspan="2">No additional flexibility outside of specified range</td><td rowspan="2">Lab personnel/Crewmembers</td></tr>
<tr><td>Nutritional Status Assessment
<u>Day 1</u>
Ht/Wt: 5 min
VxV urine: 20 min
<u>Day 2</u>
VxV urine: 20 min
<u>Day 3</u>
Close-out void
<u>Day 1, 2, or 3</u>
Blood draw: 10 min</td><td>L-90/30 d
Includes body weight/height, baseline blood collection and 48 hours of void by void urine collection</td></tr>
</table>

TABLE 3.4: PREFLIGHT ACTIVITIES (continued)

Ground Support Requirements Hardware/Software	**Preflight Hardware:**	**Preflight Software:**	**Test Location:**	
	Dietary Assessment Questionnaire (DAQ)	N/A	U.S./Russia	
	DXA (Hologic)	N/A	U.S.	
	Blood and Urine Collection Supplies	N/A	U.S./Russia	
	Body Mass Scale	N/A	U.S./Russia	
	Stadiometer	N/A	U.S./Russia	
	Centrifuge	N/A	U.S./Russia	
	Freezer	N/A	U.S./Russia	
	Refrigerator	N/A	U.S./Russia	
Testing Facilities	**Minimum Room Dimensions:**	**Number of Electrical Outlets:**	**Temperature Requirements:**	**Special Lighting:**
	8ft x 10ft	3 (U.S.-110V, Russia-220V)	Ambient	None
	Hot or Cold Running Water:	**Privacy Requirements:**	**Vibration/Acoustic Isolation:**	**Other:**
	Yes – both, and distilled water	Yes	No	Tables (2 at 3ft X 6ft); Chairs (4)
Constraints/Special Requirements:	Subject must fast for at least 8 hours before baseline blood and urine samples are collected.			
Launch Delay Requirements:	The L-90/30 data collection session will be repeated if the launch is delayed by more than 60 days, or as defined by the Flight Surgeon.			
Notes:	Further descriptions available in JSC 28566, Nutritional Status Assessment for Extended Duration Space Flight. A detailed list of the individual tests is located in the Appendix.			
Data Delivery	A report to the Crew Surgeon will be delivered 10 days after receipt of all samples. Data resides within the Mission Medical Information System (MMIS).			

3.5 In-Flight Activities

TABLE 3.5.1: IN-FLIGHT ACTIVITIES

In-Flight Activity Description:	Crewmember will perform an estimation of food intake weekly using an electronic FFQ. The results of the FFQ will be downlinked each week. Body mass will be determined monthly using a Mass Measurement device (MMD) per MEDB 1.13. These data will contribute to ongoing nutritional status assessment reports. At Flight Surgeon discretion, a more detailed dietary intake record may be ordered (obtained via written log).					
Schedule:	**Activity:**	**Duration:**	**Schedule:**	**Flexibility:**	**Blood Volume:**	**Personnel Required:**
	FFQ (on SSC)	10 minutes	Weekly and as clinically indicated	Can be placed on task list	N/A	Crewmembers
	MMD	Shared from MEDB 1.13	Monthly or as clinically indicated	Coordinate with Russian medical group		Crewmembers
	Detailed Dietary Log	30 min./day, as required	Contingency. At discretion of Flight Surgeon	N/A		Crewmembers
Procedures:	Procedures are contained within the Medical Operations procedures book or RODF (MMD).					
Constraints / Special Requirements:	N/A					
Photo / TV Requirements:	N/A					
Cold Stowage Requirements:	N/A					
Mission Extension Requirements:	N/A					
Landing Wave-Off Requirements:	N/A					
Data Delivery	Dietary data will be delivered to the Flight Surgeon within 48 hours of receipt in the Nutritional Biochemistry Laboratory. Data resides within the Mission Medical Information System (MMIS).					

TABLE 3.5.2: IN-FLIGHT HARDWARE

Hardware/Software Name
SSC
MMD

3.6 Postflight Activities

TABLE 3.6: POSTFLIGHT ACTIVITIES

<table>
<tr><td>Postflight Activity
Description:</td><td colspan="4">Postflight nutritional assessment will be conducted in conjunction with existing medical exams when possible. Biochemical testing and body composition assessment will be performed at R+0 (and repeated, at Crew Surgeon discretion). Blood samples and 48-hour VxV urine pools will be collected for determination of nutritional status and renal stone risk as described above. Body composition assessment will include weight/height and bone densitometry (DXA) on R+5/30. DXA data will be obtained per MEDB 1.11. Postflight debriefs will be conducted with crewmembers and flight surgeons, to review cumulative data. Data will be examined and the necessity/details of a diet prescription will be assessed.</td></tr>
<tr><td rowspan="3">Schedule:</td><td>Duration:</td><td>Schedule:</td><td>Flexibility:</td><td>Personnel Required:</td></tr>
<tr><td>Nutritional Status Assessment:
<u>Day 1 (R+0)</u>
Ht/Wt: shared
Blood draw: shared
VxV urine: shared
<u>Day 2</u>
VxV urine: 20 min
<u>Day 3</u>
Close-out voids</td><td>R+0, R+20/30
Includes body weight/height, baseline blood collection on Day 1 and 48 hours of void by void urine collection</td><td rowspan="2">No additional flexibility outside of specified range</td><td rowspan="2">Lab personnel/Crewmembers</td></tr>
<tr><td>DXA Scans 60 minutes
(shared with MEDB 1.11 protocol)</td><td>R+5/30</td></tr>
<tr><td>Ground Support Requirements Hardware/Software</td><td>Postflight Hardware:</td><td>Postflight Software:</td><td colspan="2">Test Location:</td></tr>
<tr><td></td><td>Same as preflight</td><td>N/A</td><td colspan="2">U.S/Russia
DXA/U.S. only</td></tr>
<tr><td rowspan="4">Testing Facilities</td><td>Minimum Room Dimensions:</td><td>Number of Electrical Outlets:</td><td>Temperature Requirements:</td><td>Special Lighting:</td></tr>
<tr><td>8’X10’</td><td>3(U.S.-110V, Russia-220V)</td><td>Ambient</td><td>None</td></tr>
<tr><td>Hot or Cold Running Water:</td><td>Privacy Requirements:</td><td>Vibration/Acoustic Isolation:</td><td>Other:</td></tr>
<tr><td>Yes – both</td><td>Room with limited access</td><td>N/A</td><td>Tables(2 at 3’x 6’)
Chairs (4)</td></tr>
<tr><td>Constraints/Special Requirements:</td><td colspan="4">R+0 blood collection should be performed as soon as possible after landing.</td></tr>
<tr><td>Early Destow / Early Return:</td><td colspan="4">N/A</td></tr>
<tr><td>Notes:</td><td colspan="4">N/A</td></tr>
<tr><td>Data Delivery</td><td colspan="4">A report to the Crew Surgeon will be delivered 10 days after receipt of all samples. Data resides within the Mission Medical Information System (MMIS).</td></tr>
</table>

3.7 Summary Schedule

TABLE 3.7: SUMMARY SCHEDULE

ACTIVITY	DURATION	SCHEDULE	FLEXIBILITY	BLOOD VOLUME	PERSONNEL REQUIRED	CONSTRAINTS
Preflight Training						
Familiarization and FFQ Training	75 minutes	AME L-21/18	No additional flexibility outside of specified range	N/A	Instructors/Crewmembers	N/A
FFQ Refresher	45 minutes	L-90/30				
Preflight						
Nutritional Status Assessment: Includes body weight/height, DAQ, baseline blood collection on Day 1 and 48 hours of void by void urine collection	**Day 1** Ht/Wt: 5 min DAQ: 45 min VxV urine: 20 min **Day 2** VxV urine: 20 min **Day 3** Close-out void **Day 1, 2, or 3** Blood draw: 10 min	AME L-21/18	No additional flexibility outside of specified range	23.2 ml	Lab personnel/ Crewmembers	Crewmembers must fast on AME L-21/18 m, L-90/30 d. Needle-stick. Blood volume is decreased by 3.0 ml when scheduled with routine physicals **Note:** DXA data obtained per MEDB 1.11.
Nutritional Status Assessment Includes body weight/height, baseline blood collection on Day 1 and 48 hours of void by void urine collection	**Day 1** Ht/Wt: 5 min VxV urine: 20 min **Day 2** VxV urine: 20 min **Day 3** Close-out void **Day 1, 2, or 3** Blood draw: 10 min	L-90/30				

TABLE 3.7: SUMMARY SCHEDULE (continued)

In-Flight	Duration	Schedule	Flexibility	Blood Volume	Personnel Required	Constraints
FFQ (on SSC)	10 minutes	Weekly and as clinically indicated	Can be placed on task list	N/A	Crewmembers	N/A
MMD	Shared	Monthly or as clinically indicated	Coordinate with Russian medical group			
Detailed Dietary Log	30 min./day, as required	Contingency. At discretion of Flight Surgeon	N/A			
Postflight						
Nutritional Status Assessment: 2 day protocol includes body weight/height, baseline blood collection on Day 1 and 48h of void by void urine collection.	<u>Day 1 (R+0)</u> Ht/Wt: shared Blood draw: shared VxV urine: shared <u>Day 2</u> VxV urine: 20 min <u>Day 3</u> Close-out voids	R+0, R+20/30	No additional flexibility outside of specified range	20.2 ml	Lab Personnel /Crewmembers	No additional R+0 time required. Ht/Wt, blood draw, and 24-h urine collection obtained as part of the routine landing physical. Additional blood required.
DXA	DXA Scans 60 min (shared with MEDB 1.11 protocol)	R+5/30				
Postflight Debrief						
Postflight debriefs will be conducted with crewmembers and Flight Surgeons to review cumulative mission data.						